REMARKS/ARGUMENTS

The Office Action dated February 8, 2006 has been received and reviewed. Claims 1-14 and 35-56 are rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

The Examiner asserts that Applicants' invention has no practical application. Applicants respectfully disagree and assert that the rejection is in error because a *prima facie* showing providing sufficient evidentiary basis for the rejection has not been made.

A rejection under 35 U.S.C. § 101 must a) make a *prima facie* showing that the claimed invention lacks utility and b) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. MPEP 2107.01 (II). Furthermore, the *prima facie* showing must be set forth in a well-reasoned statement that articulates sound reasons why a person of ordinary skill in the art would conclude that it is more likely than not that an asserted utility is not credible. Id. The statement should specifically identify the scientific basis of any factual conclusions made in the *prima facie* showing and must explain why any evidence of record that supports the asserted utility would not be persuasive to one of ordinary skill. Id. Furthermore, the Examiner must provide evidentiary support for the *prima facie* case. Id. It is imperative that the Office personnel use specificity in setting forth an initial rejection under 35 U.S.C. § 101 and support any factual conclusions in the *prima facie* showing. Id.

Applicants assert that the rejection is in error because the requisite evidentiary support for a *prima facie* showing that the claimed invention lacks utility has not been provided. The only statement supporting the rejection merely concludes that "neither the colleted data nor the evaluations produce a useful, concrete, and tangible result." Applicants assert that this statement is conclusory and does not set forth with specificity the evidentiary basis required for a rejection based on non-utility as required by the MPEP. The Examiner has not established why it is more likely than not that the asserted utilities of the invention are not credible. The Examiner has not specifically identified the scientific basis of factual conclusions or provided evidence that the asserted utility would be unpersuasive to one of ordinary skill in the art.

Applicants' invention, as recited for example in independent claim 1, is directed to a method for collecting sleep quality data. The method involves detecting physiological and non-physiological conditions related to the sleep quality of a patient. Sleep quality data is collected based on the detected conditions. Independent claim 35 recites evaluating the sleep quality data.

Applicants respectfully assert that the collection and/or evaluation of sleep quality data has clear, practical, and specific application that would be immediately apparent to one skilled in the art. As discussed in the specification on page 4, beginning at line 11, "an adequate duration and quality of sleep is required to maintain physiological homeostasis. Untreated, sleep disturbances may have a number of adverse health and quality of life consequences ranging from high blood pressure and other cardiovascular disorders to cognitive impairment, headaches, degradation of social and work-related activities and increased risk of automobile and other accidents." Thus one skilled in the art would understand that degradation of sleep quality has many adverse effects.

Furthermore, previous systems for collection and/or evaluation of sleep quality data involve the use of a polysomnographic sleep study at dedicated sleep facility. Such studies are costly, inconvenient to the patient, and may not accurately represent the patient's typical sleep behavior. (page 10 lines 12-13) Routine monitoring of patient sleep quality may lead to improved diagnosis and treatment. (page 41 lines 20-21) The invention provides less obtrusive sleep quality monitoring and is suited for patients having an implantable device. The invention serves to improve diagnosis of sleep disorders by reducing the inconveniences, unnatural sleep environment issues, and expenses associated with sleep clinic polysomnographic studies. (page 41 lines 22-26) Applicants' respectfully assert that the utility of the novel approaches to collecting and evaluating data related to sleep quality as recited in claims 1-14 and 35-56 would be understood and appreciated by one skilled in the art.

Claims 1-6, 8-14, and 35-46 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,641,542 to Cho et al. (hereinafter "Cho")

Applicants respectfully disagree with the Examiner's characterization of Cho and the contention that Cho anticipates these claims. Applicants assert that several features recited in claims 1-6, 8-14, and 35-46 are not disclosed in Cho.

To anticipate a claim, the asserted reference must clearly and unequivocally disclose every element of the claimed invention. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. All claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Independent claims 1 and 35 include, in some form, detecting physiological and non-physiological conditions related to sleep quality of a patient and collecting sleep quality data based on the detected conditions. Cho does not teach or suggest the detection of non-physiological conditions. The Examiner asserts that Cho teaches detecting body movement and that body movement is a non-physiological condition. Applicants respectfully disagree.

Applicants refer to The American Heritage Dictionary 4th edition as providing a common and ordinary meaning of the term "physiological." The American Heritage Dictionary defines the term "physiological" as "characteristic of the normal functioning of a living organism." Applicants assert that, for humans, body movement is a characteristic of normal functioning, and is thus is a "physiological condition" as the term is used in the context of the instant application.

Furthermore, Applicants describe patient activity as a "physiological condition" in the specification of the instant application. (See, e.g., page 14, Table 2). Body movement is a component of patient activity and thus is a physiological condition as the term is used by the Applicants.

Cho does not teach or suggest detecting non-physiological conditions and using such conditions in the collection and/or evaluation of sleep quality data. For at least these reasons, Cho does not provide all of the claim elements of Applicants' independent claims 1 and 35 as required to support a rejection under 35 U.S.C. § 102.

Dependent claims 2-6, 8-14, and 36-46 which are dependent from independent claims 1 or 35, were also rejected under 35 U.S.C. §102(e) as being unpatentable over Cho. While

Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 35. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2-6, 8-14, and 36-46 are also patentable over Cho.

Claim 7 was rejected under 35 U.S.C. § 103(a) based on Cho in view of US Patent 5,245,995 to Sullivan et al. (hereinafter Sullivan)

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

The combination of references do not support the rejection under 35 U.S.C. § 103(a). First, the combination of Cho and Sullivan fail to disclose all the claim limitations. As discussed above, Cho does not teach or suggest detecting non-physiological conditions. Sullivan also fails to teach this limitation.

Furthermore, Sullivan does not teach or suggest detecting environmental conditions as recited in claim 7. At col. 3 lines 34-44, Sullivan states "A patient is likely not to sleep in a fully relaxed state in an unfamiliar environment." Sullivan's statement is an observation about typical sleep habits in an unfamiliar location. Sullivan does not teach detecting environmental conditions, e.g., ambient temperature, humidity, barometric pressure, etc., and/or using these environmental conditions in the collection of sleep quality data. Sullivan does not teach or suggest collecting sleep quality data based on both detected physiological and non-physiological conditions as recited in claim 7.

Applicants respectfully assert neither Cho nor Sullivan teach or suggest all of the limitations of claim 7. Particularly in view of the missing claim elements, the teachings of Cho and Sullivan would provide insufficient guidance for one of ordinary skill in the art having these references before him/her to combine the references to achieve a successful implementation of Applicants' invention. Because the combination of Cho and Sullivan does

not provide a sufficient basis to support *prima facie* obviousness under 35 U.S.C. 103, claim 7 is patentable over the asserted combination.

Claims 47-56 are rejected under 35 U.S.C. § 103(a) based on Cho in view of US Patent 6,361,494 to Lindenthaler.

Applicants disagree that claims 47-56 are obvious in view of the combination of Cho and Lindenthaler. To support a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves itself or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings and there must be a reasonable expectation of success. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. MPEP 2143.

The asserted combination does not provide a sufficient basis to support a reasonable expectation of success or the requisite suggestion or motivation to combine or modify the references in the manner suggested by the Examiner. Applicants respectfully assert that the Examiner has failed to establish *prima facie* obviousness of Applicants' subject matter recited in claims 47-56.

First, neither Cho nor Lindenthaler suggest the desirability of the claimed invention. Cho describes an implantable approach for detecting and treating apnea based on specific incidences of sleep apnea, referred to as adverse events (See Cho, col. 6 lines 60-65) "Adverse events are measurable events indicating abnormal sleep." The severity of sleep apnea is determined from the adverse events and a decision is made whether to deliver therapy (Cho, col. 9 lines 21-23).

In contrast to Cho, the approach described by Lindenthaler is not implantable and cannot be used to detect actual, specific apnea events. Lindenthaler describes an approach for detecting airway luminal size and pharyngeal dilator muscle activity via an electrode positioned on the floor of the mouth under the tongue with an electrode line emerging through the lips. (col. 3 lines 40) According to Lindenthaler, airway luminal size and pharyngeal dilator muscle activity may be used to prediagnose sleep apnea. (See Lindenthaler, abstract) These parameters are not used to detect specific events of apnea as in Cho.

The proposed combination of Lindenthaler's sensor with the approach taught by Cho is unworkable because the combination would render Cho's system unsatisfactory for its intended purpose. The sensor described by Lindenthaler can not be used to detect the adverse events described by Cho. The use of Lindenthaler's sensor would render Cho's system inoperable to detect the adverse events. Cho's system extracts cycle length and frequency of adverse events and determines whether therapy is required. Without the detection of specific adverse events, the system of Cho would not be operable. Thus, one skilled in the art would not be motivated to combine the sensor taught by Lindenthaler in the system taught by Cho.

For at least these reasons, Applicants respectfully assert that the combination of Cho and Lindenthaler as proposed by the Examiner do not support a case of *prima facie* obviousness with regard to claims 47-56, and these claims are patentable over the asserted combination.

It is to be understood that Applicants do not acquiesce to Examiner's characterization of the asserted art or Applicants' claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to Applicants' claimed subject matter. Moreover, Applicants do not acquiesce to the Examiner's statements or conclusions concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, common knowledge at the time of Applicants' invention, officially noticed facts, and the like. Applicants reserve the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

If the Examiner has any questions or comments, a telephone call to the number indicated below is invited.

Respectfully submitted,

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